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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/655,562	09/04/2003	Sharon L. Bishop-Hurley	UVMO:022US	5742

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EXAMINER	
RUSSEL, JEFFREY E	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 11/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/655,562	BISHOP-HURLEY ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27,29 and 31-65* is/are pending in the application.

4a) Of the above claim(s) *2-4,6-9,20-22,24-27 and 50-55* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19,23,29,31-49,56 and 58-65* is/are rejected.

7)☒ Claim(s) *1,5,10-18 and 57* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Claims 2-4, 6-9, 20-22, 24-27, and 50-55 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and sequences. Election was made **without** traverse in the replies filed on May 13, 2005 and August 24, 2005.

Applicant's election without traverse of the invention of Group I and the peptide comprising SEQ ID NO:4 in the replies filed on May 13, 2005 and August 24, 2005 is acknowledged. The peptide comprising SEQ ID NO:4 has been examined and determined to be novel and unobvious over the prior art of record or any combination thereof. Accordingly, linking claims 47-49, 56, and 57, and claims 58-65, to the extent that they recite a peptide comprising SEQ ID NO:4, have been rejoined and examined with the elected invention.

Search and examination has not been extended to nonelected SEQ ID NOS:1-3 and 5-8. Note that the Office action mailed April 11, 2005 sets forth a restriction requirement among these SEQ ID NOS. There is no significant common sequence or structure among these claimed SEQ ID NOS, and each SEQ ID NO would require separate and non-overlapping sequence searches plus consideration of their results.

2. Claims 29, 31, and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. There is no antecedent basis in the claims for the phrase "said Staphylococcal species" in claim 29 or for the phrase "said Haemophilus species" in claim 31. Note that independent claim 19 was not amended to recite Staphylococcal or Haemophilus species.

3. Claims 36-38 are objected to because of the following informalities: At claim 36, line 2, "local" should be changed to "locally", and "regional" should be changed to "regionally". Appropriate correction is required.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 19, 23, 33-49, and 58-65 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibiting or preventing the growth, preventing bacterial infection, preventing bacterial attachment, and identifying bacterial receptors where the bacteria are Staphylococcal or Haemophilus species, does not reasonably provide enablement for performing these functions for all bacteria. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150 (CCPA 1977) and have been adopted by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. With respect to (1), the nature of the invention is inhibiting or preventing the growth, preventing bacterial infection, preventing bacterial attachment, and identifying bacterial receptors for all bacteria. With respect to (2), the prior art does not disclose a peptide comprising SEQ ID NO:4.

The prior art also does not disclose any universal antibacterial substances, i.e. one that will bind to and/or inhibit the growth of all bacteria. With respect to (3), the relative skill of the art is high. With respect to (4), the predictability of the art is relatively low. One skilled in the art can not predict what antibacterial activity a compound may exhibit in the absence of testing. With respect to (5), the claims are relatively broad, embracing all types of bacteria, including gram-positive bacteria, gram-negative bacteria, etc. With respect to (6) and (7), other than tests with Staphylococcus aureus and Haemophilus influenzae, there are no working examples concerning other bacterial species. The specification does not give any direction or guidance as to how the claimed peptides can be used against bacteria which are unrelated to Staphylococcus or Haemophilus species. With respect to (8), given the breadth of the bacteria recited in the claims and given the expectation in the art that a compound effective against one or two species of bacteria would likely not be effective against large numbers of unrelated species, the quantity of experimentation necessary to use the invention would be vast. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claim 56 is rejected under 35 U.S.C. 102(e) as being anticipated by Adler et al (U.S. Patent Application Publication 2003/0143671). Adler et al teach beta-defensin peptides which inhibit pathogenic infection by Haemophilus influenzae and Staphylococcus aureus. See, e.g., claims 26 and 29. In view of the similarity in structure and activity between the peptides of Adler et al and Applicants' claimed peptide, inherently the former are deemed to have bacteriocidal effects on H. influenzae and bacteriostatic effects on S. aureus to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the peptides of Adler et al and Applicants' claimed peptide to shift the burden to Applicants to provide evidence that the claimed peptide is unobviously different than the peptides of Adler et al. Note that process limitations do not impart patentability to product-by-process claims where the product is otherwise anticipated by the prior art.

8. Claim 56 is rejected under 35 U.S.C. 102(b) as being anticipated by Fraser et al (U.S. Patent Number 6,180,604). Fraser et al teach indolicidin peptide analogs which inhibit infection by, e.g., Haemophilus influenzae and Staphylococcus aureus. See, e.g., the Abstract and column 3, lines 45-57. In view of the similarity in structure and activity between the peptides of Fraser et al and Applicants' claimed peptide, the former are deemed inherently to have bacteriocidal effects on H. influenzae and bacteriostatic effects on S. aureus to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the peptides of Fraser et al and Applicants' claimed peptide to shift the burden to Applicants to provide evidence that the claimed peptide is unobviously different than the peptides of Fraser et al. Note that process limitations do not impart patentability to product-by-process claims where the product is otherwise anticipated by the prior art.

9. Applicant's arguments filed October 13, 2006 have been fully considered but they are not persuasive.

The rejection under 35 U.S.C. 112, first paragraph, is maintained. While Applicants have stated at page 11 of the response that the claims have been amended to address the perceived deficiencies, no amendment ahs been made to independent claims 19, 42, 47, and 58, and no amendment concerning bacterial species has been made to independent claims 43 and 44. Applicants have not otherwise traversed the rejection.

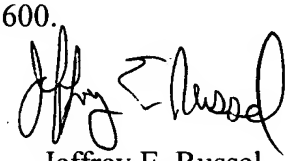
10. Claims 1, 10-18, and 57 are objected to because of their recitation of nonelected sequences, but would be allowable if re-written to recite only the elected sequence. Claim 5 is objected to as being dependent upon an objected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

November 2, 2006